

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Paul DiCarlo et al.

Art Unit : 1794

Serial No. : 10/791,103

Examiner : Leszek B. Kiliman

Filed : March 2, 2004

Conf. No. : 2432

Title : EMBOLIC COMPOSITIONS

Mail Stop Appeal Brief - Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

BRIEF ON APPEAL

(1) Real Party in Interest

Boston Scientific Scimed, Inc.

(2) Related Appeals and Interferences

None.

(3) Status of Claims

Claims 1-10, 17, 25-27, and 29-39 are pending, and claims 11-16, 18-24 and 28 are cancelled.

Appellant appeals the final rejection of claims 1-10, 17, 25-27, and 29-39 provided by the Examiner in the final Office Action dated August 24, 2009 ("the Final Office Action") and maintained in the Advisory Action dated October 9, 2009 ("the Advisory Action").

Each of claims 1-10, 17, 25-27, and 29-39 has been twice rejected, is currently rejected, and is presented for appeal.

(4) Status of Amendments

All amendments have been entered.

(5) Summary of Claimed Subject Matter

The disclosure provides embolic compositions and methods of using the compositions.

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See, e.g., USSN 10/791,103, p. 1, line 9. A composition can include a generally spherical embolic particle that includes a shape memory material. *See, e.g., id.*, p. 1, lines 21-22, p. 4, lines 27-28, p. 11, lines 12-15, and Figs. 1A, 18, and 19. Various types and examples of shape memory materials, including polymers and alloys, are provided. *See id.*, p. 5, line 15-p. 6, line 22. Polyvinyl alcohol is disclosed as an example of a non-shape memory material. *See id.*, p. 12, line 27-p. 13, line 1. In certain embodiments, a composition can include generally spherical embolic particles in a vessel with a suitable carrier, such as saline. *See id.*, p. 4, lines 25-27 and Fig. 1A. A change in the shape of the particle can be selectively triggered to facilitate treatment, such as embolization. *See Id.*, p. 4, lines 28-31 and Fig. 1B.

Claim 1, which is the only claim in independent form, reads as follows:

A composition comprising an embolic particle comprising a shape memory material,

wherein the particle is generally spherical and the shape memory material is not polyvinyl alcohol.

Thus, all the claims require a generally spherical embolic particle that includes a shape memory material that is not polyvinyl alcohol.

(6) Grounds of Rejection to be Reviewed on Appeal

Claims 1-10, 17, 25-27 and 29-39 are rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite.

Claims 1-10, 17, 25-27 and 29-39 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Bourne et al., U.S. Patent No. 7,131,997 ("Bourne")

(7) Argument

Rejection under 35 U.S.C. §112, second paragraph

The Examiner rejected independent claim 1 and its dependent claims 2-10, 17, 25-27 and

29-39 under 35 U.S.C. §112, second paragraph as allegedly being indefinite. In particular, the Examiner stated “The statement ‘the shape memory alloy material is not polyvinyl alcohol’ is not a positive statement and does not in any way ha[ve] patentable meaning.” *See* the Office Action mailed August 24, 2009, p. 2.

Applicants disagree with the Examiner’s position. As explained in the M.P.E.P.:

... there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. 112, second paragraph. *See* M.P.E.P. § 2173.05(i).

Here, the boundaries of the term “the shape memory alloy material is not polyvinyl alcohol”, as it appears in independent claim 1, are set forth definitely – the shape memory alloy material is simply not polyvinyl alcohol. Indeed, while the application as filed provided various types and examples of shape memory materials, the application also explicitly referred to polyvinyl alcohol as “a material that does not exhibit shape memory characteristics”. *See* USSN 10/791,103, p. 5, line 15-p. 6, line 22 and p. 12, line 27-p. 13, line 1.

Further, claim 3 requires the shape memory material to be a polymer that is selected from “polyurethane, polynorbornene, polymethylmethacrylate, poly(vinyl chloride), polyethylene, polyisoprene, styrene-butadiene copolymer, a rubber, and a photocrosslinkable polymer”; claim 4 requires the shape memory material to “comprise[] an alloy”; and claim 5 requires the alloy to be “a nickel-titanium alloy”. Hence, claims 3-5 actually positively recite the shape memory materials covered by these claims.

In view of the foregoing, Appellant requests reversal of the rejection of claims 1-10, 17, 25-27 and 29-39 under 35 U.S.C. §112, second paragraph.

Rejection under 35 U.S.C. §102(c)

The Examiner rejected independent claim 1 and its dependent claims 2-10, 17, 25-27 and 29-39 under 35 U.S.C. §102(c) as allegedly being anticipated by Bourne. *See* the final Office Action, p. 3. However, Bourne simply does not disclose, for example, one or more generally spherical particles that include a shape memory material that is not polyvinyl alcohol, as required

by independent claim 1. Nor has the Examiner even pointed to a disclosure of shape memory material in Bourne. Instead, in a prior Office Action (on which Applicants assume the Examiner relies when maintaining the rejection "substantially for the reasons of record")¹, the Examiner generically referred to more than 40 lines of text in Bourne as allegedly disclosing a shape memory material. *See* the Office Action mailed March 23, 2009, p. 3. However, this section of Bourne merely discloses certain porous particles that can have a "symmetric compressibility profile". *See* Bourne at col. 6, lines 44-45. As would be understood by one skilled in the art, this is not tantamount to an explicit disclosure of a shape memory material that is not polyvinyl alcohol. To the extent the Examiner holds a contrary view, the Examiner is reminded that, as explained at MPEP §2144.03 (emphasis in original):

[i]t would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at 420-21. *See also In re Grose*, 592 F.2d 1161, 1167-68, 201 USPQ 57, 63 (CCPA 1979) ("[W]hen the PTO seeks to rely upon a chemical theory, in establishing a *prima facie* case of obviousness, it must provide evidentiary support for the existence and meaning of that theory."); *In re Eynde*, 480 F.2d 1364, 1370, 178 USPQ 470, 474 (CCPA 1973) ("[W]e reject the notion that judicial or administrative notice may be taken of the state of the art. The facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men and are not amenable to the taking of such notice.").

It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 ("[T]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings."). While the court explained that, "as an administrative tribunal the Board clearly has

¹ Appellant finds the Examiner's use of the word "substantially" confusing and yet again requests clarification on this point. Is the Examiner raising any new grounds of rejection based on information allegedly disclosed in Bourne? If the answer to this question is yes, Appellant believes the Examiner must state such grounds explicitly. If the answer to the question is no, then Appellant does not understand why the Examiner uses the term "substantially" and ask that the Examiner explain why he is using the term "substantially".

expertise in the subject matter over which it exercises jurisdiction," it made clear that such "expertise may provide sufficient support for conclusions [only] as to peripheral issues." *Id.* at 1385-86, 59 USPQ2d at 1697. As the court held in Zurko, an assessment of basic knowledge and common sense that is not based on any evidence in the record lacks substantial evidence support. *Id.* at 1385, 59 USPQ2d at 1697.

In other words, Appellant believes the Examiner should provide evidence to support this position.

Nor has the Examiner established that Bourne inherently discloses a shape memory material that is not polyvinyl alcohol. As stated by the United States Court of Appeals for the Federal Circuit in *Electro Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052 (Fed. Cir. 1994), "[t]he mere fact that a thing may result from a given set of circumstances is insufficient to prove anticipation." (citations omitted; emphasis original). Instead, one asserting that a reference inherently discloses certain subject matter must prove that the features are "necessarily present [in the prior art reference] and that it would be so recognized by persons of ordinary skill." (*Id.*) Here, the Examiner has not satisfied the requisite legal standard. Furthermore, in the portion of Bourne relied upon by the Examiner, Bourne discloses polyvinyl alcohol particles. In contrast the claims cover a shape memory material that is not polyvinyl alcohol.

Further, the claims which depend from claim 1 feature additional limitations which are even further removed from Bourne. As an example, claim 3 requires the shape memory material to be a polymer that is selected from "polyurethane, polynorbornene, polymethylmethacrylate, poly(vinyl chloride), polyethylene, polyisoprene, styrene-butadiene copolymer, a rubber, and a photocrosslinkable polymer". As an additional example, claim 4 requires the shape memory material to "comprise[] an alloy". As a further example, claim 5, which depends from claim 4, requires the alloy to be "a nickel-titanium alloy". Appellant finds no such disclosure of such shape memory materials in Bourne, and the Examiner has not even attempted to point to where such disclosure is believed to be present.

Accordingly, Appellant requests reversal of the rejection of claims 1-10, 17, 25-27 and 29-39 under 35 U.S.C. §102(e).

The brief fee of \$540 is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

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Respectfully submitted,

Date: November 6, 2009

/Sean P. Daley/

Sean P. Daley
Reg. No. 40,978

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110
Telephone: (617) 542-5070
Facsimile: (877) 769-7945

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Appendix of Claims

1. (Previously Presented) A composition comprising an embolic particle comprising a shape memory material,
wherein the particle is generally spherical and the shape memory material is not polyvinyl alcohol.
2. (Original) The composition of claim 1, wherein the shape memory material comprises a polymer.
3. (Original) The composition of claim 2, wherein the polymer is a material selected from the group consisting of polyurethane, polynorbornene, polymethylmethacrylate, poly(vinyl chloride), polyethylene, polyisoprene, styrene-butadiene copolymer, a rubber, and a photocrosslinkable polymer
4. (Original) The composition of claim 1, wherein the shape memory material comprises an alloy.
5. (Original) The composition of claim 4, wherein the alloy is a material selected from the group consisting of a nickel-titanium alloy.
6. (Original) The composition of claim 1, wherein the particle is non-bioabsorbable in a body.
7. (Original) The composition of claim 1, wherein the particle comprises a therapeutic agent.
8. (Original) The composition of claim 7, wherein the particle defines a cavity, and the therapeutic agent is in the cavity.

9. (Original) The composition of claim 1, wherein the particle comprises a radiopaque material.

10. (Original) The composition of claim 9, wherein the radiopaque material is selected from the group consisting of gold, tantalum, platinum, and tungsten.

11-16. (Cancelled).

17. (Original) The composition of claim 1, wherein the particle has a groove.

18-24. (Cancelled).

25. (Previously Presented) The composition of claim 1, wherein the particle comprises a portion capable of dissolving in a body.

26. (Original) The composition of claim 1, wherein the particle further comprises a second material that does not include a shape memory material.

27. (Previously presented) The composition of claim 26, wherein the second material is selected from the group consisting of polyester, nylon, polytetrafluoroethylene, polypropylene, poly-paraphenylene terephthalamide, silk, collagen, hair, and alginate.

28. (Cancelled).

29. (Previously Presented). The composition of claim 1, comprising a plurality of embolic particles, wherein at least one of the particles comprises the shape memory material, and the plurality of embolic particles do not include polyvinyl alcohol.

30. (Original) The composition of claim 29, further comprising a second plurality of embolic particles, a particle in the second plurality having a different shape than a particle in the plurality of embolic particles.

31. (Previously Presented) The composition of claim 29, comprising the generally spherical particle and a non-spherical particle.

32. (Original) The composition of claim 29, further comprising a second plurality of embolic particles, a particle in the second plurality having a different size than a particle in the plurality of embolic particles.

33. (Original) The composition of claim 29, further comprising a second plurality of embolic particles, a particle in the second plurality having a different hardness than a particle in the plurality of embolic particles.

34. (Original) The composition of claim 1, further comprising a second, non-solid embolic material.

35. (Original) The composition of claim 34, wherein the second embolic material is in the form of a liquid, a gel, or a foam.

36. (Original) The composition of claim 1, wherein the particle comprises a material capable of increasing in volume upon exposure to a predetermined stimulus.

37. (Original) The composition of claim 36, wherein the material comprises a hydrogel.

38. (Previously presented) The composition of claim 26, wherein the second material is selected from the group consisting of polyester, nylon, polytetrafluoroethylene, polypropylene, silk, collagen, hair, and alginate.

39. (Previously presented) The composition of claim 27, wherein the second material comprises polyethylene terephthalate.

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Evidence Appendix

None.

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Related Proceedings Appendix

None.